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TRANSITIONAL REVIEW MECHANISM PURSUANT TO PARAGRAPH 18 OF THE PROTOCOL ON THE ACCESSION OF THE PEOPLE'S REPUBLIC OF CHINA ("CHINA")

Questions From the UNITED STATES to CHINA

The following communication, dated 14 November 2007, is being circulated at the request of the delegation of the United States.

In document G/C/W/587, the United States submitted questions to China in connection with the 23 November 2007 meeting of the Council for Trade in Goods for the purposes of the transitional review mandated by China's Protocol of Accession. The United States wishes to pose the following additional questions to China. Some of these questions relate to matters that were raised by the United States and other Members, but not answered by China, during the transitional reviews held before the TRIMS Committee and the TBT Committee, which were held after the United States submitted document G/C/W/587.

1. Export Duties on Lead Metal

1. The United States understands that China decided in 2006 to eliminate the 13 percent value-added tax (VAT) rebate available upon export of refined metal lead and then, in 2007, imposed a duty of 10 percent on exports of refined metal lead. These actions caused a steep decline in China's exports of refined metal lead and have contributed to a sharp rise in world prices, which have gone from approximately US$1,300 per metric ton (MT) at the time of China's elimination of the export VAT rebate in 2006 to approximately US$3,200 per MT in recent months. Meanwhile, Chinese domestic prices have reportedly declined because of China's captive refined metal lead production, giving China's downstream producers a significant competitive advantage over foreign downstream producers.

(a) Please explain the purposes underlying China's elimination of the export VAT rebate for refined metal lead and China's imposition of export duties on refined metal lead.

(b) In Section 11.3 of Part I of its Protocol of Accession, China committed not to impose export duties on any goods not appearing on the list of goods subject to export duty in Annex 6 of its Protocol of Accession. Refined metal lead does not appear on the Annex 6 list. Please explain how China justifies its imposition of export duties on this product in light of the commitment that China made in Section 11.3 of Part I of its Protocol of Accession.

2. Import Restrictions on Technologies

2. On 2 November 2007, MOFCOM issued a *Catalogue of Technologies Whose Imports Are Banned or Restricted*, which lists technologies whose imports are banned or restricted. In a statement accompanying the release of this catalogue, MOFCOM stated that the catalogue is intended to implement China's 2006-2020 medium- and long-term science and technology development plans by "restricting blind imports, guiding enterprises to import advanced and appropriate foreign technologies, and promoting assimilation of imported technologies and re-innovation." The catalogue reportedly contains 126 types of technologies in 19 industries. It bans technology imports that would "endanger national security, affecting social and public morality and social public interest, affecting human or animal and plant lives and health, or damaging ecology and environment." It restricts technology imports "for the purpose of establishing or accelerating the establishment of specific domestic industries," "for ensuring the nation's international financial status and international balance of payments" or if such imports "do not comply with industrial policies."

(a) Please identify the technology imports that are banned under the catalogue.

(b) Please explain how China justifies these bans in light of its obligations under Article XI of the General Agreement on Tariffs and Trade 1994.

(c) Does China ban the sale of the same technology products if produced domestically? If not, why not?

(d) Please identify the technology imports that are restricted under the catalogue.

(e) Has China decided on the import restrictions that will be imposed on these imports? If so, please describe them, and explain how China justifies them in light of its obligations under Article XI of the General Agreement on Tariffs and Trade 1994.

3. M&A Regulations

3. In August 2006, new regulations on mergers and acquisitions (M&A regulations) were jointly issued by China's Ministry of Commerce (MOFCOM), the State-owned Assets Supervision and Administration Commission, the State Administration of Taxation, the State Administration of Industry and Commerce, the China Securities Regulatory Commission and the State Administration of Foreign Exchange. The regulations strengthen MOFCOM's supervisory role over foreign investment, in part by requiring MOFCOM's approval of M&A transactions that it believes impact state economic security or involve famous Chinese brands. The regulations also place MOFCOM in the role of determining if the domestic acquisition target has been appropriately valued. In the interest of transparency, and so that the United States and other WTO Members can better understand how China's M&A regulations may or may not be relevant to the TRIMS Agreement or commitments that China made in its WTO accession agreement, the United States seeks the following clarifications from China:

(a) Article 12 of the M&A regulations calls for MOFCOM's approval of any deal involving a "major industry", having "impact on the state economic security" or concerning "famous trademarks or traditional Chinese brands." This language is very broad and appears to require MOFCOM approval on most foreign investment transactions. Please explain what the quoted terms mean. Does China intend to define these terms in the implementing rules?

(b) Article 14 of the M&A regulations requires that MOFCOM approve the valuation of any merger or acquisition. What qualifications and experience will be required of

those who determine the appropriate valuation? On what basis will they determine the value?

(c) Chapter 5 of the M&A regulations requires reporting of any M&A transaction that meets specific criteria or involves "very large market share" or ""other important factors" that affect competition. Will the recently enacted Anti-Monopoly Law (AML) supersede these reporting requirements and the anti-monopoly examination of foreign M&A transactions under these regulations? If not, what will be the relationship between the anti-monopoly reviews under Chapter 5 and the AML?

(d) Will any anti-monopoly review of mergers be carried out separately from the national economic security review under Article 12 of the M&A Regulations? Please explain.

(e) What plans do the relevant Chinese agencies have for issuing implementing rules for the M&A regulations, in addition to the guidelines issued in March 2007 on the requirements for filing reports under Article 51? Will opportunities be provided for public comment on drafts of these implementing rules?

4. Medical Device Border Examination

4. China's Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) issued the *Administrative Measures on Examination and Supervision of Imported Medical Devices* in late June 2007, to be effective 1 December 2007. Known as Decree 95, this measure imposes an examination and supervision regime on imported medical devices. China cites as underlying statutory authority for this measure its 2002 Law on Import and Export Commodity Inspection.

5. Decree 95 establishes three risk categories of medical devices and three categories for importers, based on their experience and other factors. It requires certain percentages (ranging from 10 to 100 percent) of imported medical devices in each risk category to be subject to inspection. The intensity and type of inspection vary based both on the category of the importer and the risk category of the product. For example, 100 percent of medical devices categorized in the highest risk category (e.g., MRIs and pacemakers) are subject to inspection. Decree 95 also calls for a product catalogue that specifies which medical devices are subject to particular inspection regimes. These inspections would be in addition to the existing certification requirements that foreign manufacturers must obtain, prior to exporting medical devices to China, through the normal regulatory process at the State Food and Drug Administration and the Certification and Accreditation Administration. In addition, Decree 95 sets out requirements for foreign manufacturers to report product defects, requirements on donated medical devices and requirements on remanufactured medical devices. Decree 95 appears to go substantially further than common international practice, where border inspection is generally done only on a very small percentage of already-certified devices, and done in response to targeted concerns.

6. The United States has serious substantive concerns about this measure, as well as concerns about China's failure to notify the measure to the WTO.

(a) Article 23 of Decree 95 provides authority for AQSIQ to conduct nine different types of inspection at the time a covered product is imported, including electromagnetic compatibility, emissions, and performance assessment of diagnostics. This inspection authority, whether it is exercised for 10 percent, 30 percent, 50 percent or 100 percent of imported medical devices (depending on risk categorization and company classification) as indicated in the measure, would mean exhaustive border inspection in a manner going substantially beyond common international practice. Please clarify how frequently AQSIQ and its designees will conduct actual inspections of medical

devices at the point of entry, and how frequently AQSIQ and its designees will merely conduct verification of required paperwork.

(b) Please identify and describe any regulations or other measures that require inspection of domestic medical devices manufactured and sold within China, after those medical devices have received type approval and SFDA certification.

(c) Does China have any regulations or other measures that regulate the domestic distributors of domestically manufactured medical devices in a manner similar to the scheme set out in Decree 95 for the importers of imported medical devices? Please explain.

(d) Please describe the fee that will be assessed when AQSIQ conducts an examination and supervision. How much will an individual examination cost? What is the purpose of the fee and on what basis is it calculated?

(e) In bilateral discussions with the United States, China has argued, among other things, that it sees no need to notify the measure, given that the overarching law (its 2002 Law on Import and Export Commodity Inspection) was notified to the WTO. However, the TBT Agreement notification obligation applies to any measure that fits the definition of a technical regulation under Annex 1 of the Agreement, subject to the provisions of Article 2.9. Thus, a WTO Member's characterization of a measure as a law, a regulation or some other type of measure is not determinative. The United States routinely notifies to the WTO changes made by not only laws enacted by the US Congress, but also regulations and other measures issued by regulatory agencies. Please explain China's justification for not notifying Decree 95 to the WTO.

(f) China has also argued that notification of Decree 95 is not required because this measure does not impose any requirements on foreign manufacturers, and only impacts domestic Chinese entities involved in importation. By its terms, the measure requires the examination of imported medical devices, based on a scale from low-risk to high-risk medical devices. The measure also requires foreign manufacturers to report defects, and imposes penalties in the form of increased examinations of imported devices based on product returns or quality complaints. The measure additionally regulates medical devices imported for research purposes, as well as used medical devices, and provides authority to AQSIQ to stop the import of defective medical devices based on reporting from a risk alert system. The underlying law on which this measure is based, the Law on Import and Export Commodity Inspection, is focused on the inspection of import and export commodities. Given these facts, please explain China's position that this measure does not impose any requirements on foreign manufacturers, and only impacts domestic Chinese entities involved in importation.

(g) Will China notify Decree 95 to the WTO and permit WTO Members and interested persons the opportunity to present comments in writing, and for China to hear the concerns of Members and interested persons and make appropriate modifications to the regulations, and for China to allow exporters time to adapt their products and export procedures to China's requirements? Given the short time before the measure's effective date, will China consider suspending the measure, including its 1 December 2007, effective date, so that this process can take place?